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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,547	01/12/2004	Longgui Wang	15741.004	9273

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EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/754,547	WANG ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,13,14 and 17-34* is/are pending in the application.

4a) Of the above claim(s) *4,6,21,23 and 31-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7-11,13,14,17-20,22 and 24-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments filed June 27, 2007 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-11, 13, 14 and 17-30 are pending in this application. Claims 4, 6, 21, 23 and 31-34 are withdrawn from consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3, 5, 7-11, 13, 14, 17-20, 22 and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. U.S. Patent No. 6,566,341.

Wang et al. teach inter alia meisoindigo for treatment of inflammatory diseases such as cardiovascular disease, Alzheimer's disease, psoriasis, cardiovascular diseases and glomerulonephritis (column 4, lines 25-33). Each of these maladies is identified in the instant claims as inflammatory disorders/diseases.

Regarding the instant claims drawn to administration of the anti-inflammatory agent, meisoindigo, with an additional anti-inflammatory agent such as ibuprofen (see instant claims 27 and 28),

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980):

> It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. In re Susi, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960). As this court explained in Crockett, the idea of combining them flows logically from their having been individually taught in the prior art.

As such, It would have been made obvious to one of ordinary skill in art at the time it was made to combine two anti-inflammatory agents in order to form a third agent for the method of treating anti-inflammatory conditions.

Regarding the method of inhibiting pro-inflammatory cytokine expression or stimulating anti-inflammatory cytokine expression or inhibiting cyclin dependent kinases, since Wang et al. administers the same agents to treat illnesses such as Alzheimer's disease, psoriasis, cardiovascular diseases, and glomerulonephritis, the effect of inhibiting pro-inflammatory cytokine expression or stimulating anti-inflammatory cytokine expression or inhibiting cyclin dependent kinases would occur. Products of identical chemical composition (i.e. meisoindigo) can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. inhibiting pro-inflammatory cytokine expression or stimulating anti-inflammatory cytokine expression or inhibiting cyclin dependent kinases) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) (Applicant argued that the claimed composition was a pressure sensitive adhesive

containing a tacky polymer while the product of the reference was hard and abrasion resistant. "The Board correctly found that the virtual identity of monomers and procedures sufficed to support a prima facie case of unpatentability of Spada's polymer latexes for lack of novelty.").

Regarding claims 8 and 25, drawn to administration of an agent concurrently or sequentially, it is unclear to the examiner how else one would administer two different agents. It would have been obvious to administer the two anti-inflammatory agents together, either concurrently or sequentially.

Regarding claim 14, drawn to Crohn's disease or ulcerative colitis, although Wang et al. does not teach treatment of Crohn's disease or ulcerative colitis with the agent meisoindigo specifically, it is prima facie obvious to substitute equivalents, motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances. *In re Ruff* 118 USPQ 343; *In re Jezel* 158 USPQ 99; the express suggestion to substitute one equivalent for another need not be present to render the substitution obvious: *In re Font*, 213 USPQ 532. It would have been made obvious to one of ordinary skill in art at the time it was made to administer meisoindigo for the inflammatory conditions Crohn's disease and ulcerative colitis motivated by the teaching of Wang et al. that the agent meisoindigo is employed for other inflammatory conditions such as cardiovascular disease, Alzheimer's disease, psoriasis, cardiovascular diseases and glomerulonephritis.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5, 7-20, 22 and 24-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of copending Application No. 11/494362. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claim 1 requires method of treating inflammatory arthritis comprising administering inter alia, meisoindigo. None of the instant claims recites specifically inflammatory arthritis, but instant claims 1-3, 5, 7-20, 22 and 24-30 are broadly inclusive thereof. It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in

this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

New Claim Objections

Claim 1 is objected to because of the following informalities: the words "arthritis" is repeated twice in the claim. Appropriate correction is required.

Claim 13 is objected to because of the following informalities: The word uncerative in line 4 of the claim appears to be misspelled. It is believed that the correct spelling is "ulcerative". Appropriate correction is required.

Claim 20 is objected to because of the following informalities: The word uncerative in line 2 of the claim appears to be misspelled. It is believed that the correct spelling is "ulcerative". Appropriate correction is required.

New Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-3, 5, 7-20, 22 and 24-30 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 10-36 of copending Application No. 11/104422. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Response to Arguments

Applicant asserts that the '341 patent is directed to derivatives of isoindigo, indigo and indirubin, primarily for the treatment of cancer. In response, Wang et al. teach inter alia meisoindigo for treatment of inflammatory diseases such as cardiovascular disease, Alzheimer's disease, psoriasis, cardiovascular diseases and glomerulonephritis (column 4, lines 25-33).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., compounds disclosed in the '341 patent regulate cytokine expression) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant indicates that the dosage of meisoindigo to treat inflammatory bowel disease is typically only 25 mg/day and if the dosage of the compound sufficient to inhibit CDK is administered, the compound typically negatively affects the inflammation

healing process. This feature is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims.

Applicant indicates that the claims have cancelled a reference to Alzheimer's disease, psoriasis, cardiovascular diseases or glomerulonephritis; however, claim 1 is still directed to treatment of atherosclerosis, a cardiovascular disorder.

Regarding the double patenting rejections, Applicant indicates that a clear line of demarcation will be maintained in view of claims 10-36 of Application No. 11/104,422 and with regard to Application No. 11/494/362, a terminal disclaimer upon allowance of the claims will be filed, if necessary.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Donna Jagoe
Patent Examiner
Art Unit 1614

August 6, 2007